

DOCKET NO: UPAP0025-100 (K1763)
PATENT APPLICATION

Serial No.: 09/719,067
Filed: August, 16 2001

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Please cancel claim 3.

Please amend claims 11 and 31.

STATUS OF CLAIMS

Claim 1. (currently amended) A method of delivering a protein to a macrophage cell or a cell of macrophage derived lineage of an individual comprising the steps of:

administering to said individual at a site on said individual's body, a DNA molecule, wherein said DNA molecule is a plasmid comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage, wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cell and/or said cell of macrophage derived lineage.

Claim 2 (original) The method of claim 1 wherein said DNA molecule is administered by a route of administration selected from the group consisting of: intradermal, subcutaneous, intraperitoneal, intramuscular, and oral.

Claim 3 (canceled)

Claim 4 (canceled)

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Claim 5 (previously presented) A method of delivering a protein to a macrophage cell or a cell of macrophage derived lineage of an individual comprising the steps of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage, wherein said macrophage specific promoter is selected from the group consisting of a catalase promoter, a CD156 promoter, a M-CSFR promoter, a p73 promoter, and an FcγRI promoter, wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cell and/or said cell of macrophage derived lineage.

Claim 6 (original) The method of claim 1 wherein said polyadenylation signal is selected from the group consisting of: an SV40 polyadenylation signal and a bovine growth hormone polyadenylation signal.

Claim 7 (original) The method of claim 1 wherein said DNA molecule is administered with a composition which facilitates uptake of said DNA molecule by a cell.

Claim 8 (original) The method of claim 1 wherein said DNA molecule is administered with bupivacaine.

Claim 9. (previously presented) A method of delivering a protein to a lymphnode of an individual comprising the steps of:

- a) identifying said lymphnode that is to have protein delivered to;
- b) locating a site on said individual's body that is proximal to said lymphnode;
- c) administering to said individual at said site, a DNA molecule comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is operably

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linked to a promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage,

wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cell and/or said cell of macrophage derived lineage, and said macrophage cell and/or said cell of macrophage derived lineage drains to said lymphnode, and delivers said protein in said lymphnode.

Claim 10 (original) The method of claim 9 wherein said DNA molecule is administered by a route of administration selected from the group consisting of: intradermal, subcutaneous, intraperitoneal, intramuscular, and oral.

Claim 11 (currently amended) ~~The method of claim 9~~ A method of delivering a protein to a lymphnode of an individual comprising the steps of:

- a) identifying said lymphnode that is to have protein delivered to;
- b) locating a site on said individual's body that is proximal to said lymphnode;
- c) administering to said individual at said site, a DNA molecule, wherein said DNA molecule is a plasmid, comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage,

wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cell and/or said cell of macrophage derived lineage, and said macrophage cell and/or said cell of macrophage derived lineage drains to said lymphnode, and delivers said protein in said lymphnode.

Claim 12 (original) The method of claim 9 wherein said promoter is a macrophage promoter.

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Claim 13 (original) The method of claim 9 wherein said promoter is selected from the group consisting of: an actin promoter, a CD11 promoter, a CD13 promoter, an MHC-I promoter, an MHC-II promoter, a CD25 promoter, a CD80 promoter, a CD86 promoter, a catalase promoter, a CD156 promoter, an M-CSFR promoter, a p73 promoter, an FcγRI promoter, a CMV promoter, an actin promoter, an SV40 promoter and a Malony virus promoter.

Claim 14 (original) The method of claim 9 wherein said polyadenylation signal is selected from the group consisting of: an SV40 polyadenylation signal and a bovine growth hormone polyadenylation signal.

Claim 15 (original) The method of claim 9 wherein said DNA molecule is administered with a composition which facilitates uptake of said DNA molecule by a cell.

Claim 16 (original) The method of claim 9 wherein said DNA molecule is administered with bupivacaine.

Claim 17 (original) The method of claim 9 wherein said protein comprises a secretion signal sequence.

Claim 18 (previously presented) A method of inducing an immune response against an immunogen in an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said immunogen operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in macrophage cells and/or cells of macrophage derived lineages,

wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said

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immunogen in said macrophage cell and/or said cell of macrophage derived lineage and an immune response mediated by said macrophage is generated against said immunogen.

Claim 19 (previously presented) The method of claim 18 wherein said DNA molecule further comprises

a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in macrophage cells and/or cells of macrophage derived lineages, and/or

a second DNA molecule is additionally administered to said site on said individual's body, said second DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said second DNA molecule is operably linked to a promoter that is functional in macrophage cells and/or cells of macrophage derived lineages and a polyadenylation signal that is functional in macrophage cells and/or cells of macrophage derived lineages.

Claim 20 (original) The method of claim 18 wherein said immune response targets a pathogen.

Claim 21 (original) The method of claim 18 wherein said immune response is a protective immune response.

Claim 22 (original) The method of claim 18 wherein said immune response is a therapeutic immune response.

Claim 23. (previously presented) A method of modulating an individual's immune system comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is operably linked to a macrophage specific promoter and a

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polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage,

wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said immunomodulating protein modulates said individual's immune system.

Claim 24. (previously presented) The method of claim 23 wherein said DNA molecule further comprises

a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in macrophage cells and/or cells of macrophage derived lineages and/or

a second DNA molecule is additionally administered to said site on said individual's body, said second DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said second DNA molecule is operably linked to a promoter that is functional in macrophage cells and/or cells of macrophage derived lineages and a polyadenylation signal that is functional in macrophage cells and/or cells of macrophage derived lineages.

Claim 25. (previously presented) A method of eliminating cells in a lymphnode of an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes a cytotoxic protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage,

wherein said DNA molecule is taken up by a macrophage cells and/or a cells of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cells and/or said cells of macrophage derived lineage,

said macrophage cell and/or a cell of macrophage derived lineage secretes or releases said cytotoxic protein in said lymphnode eliminating cells in said lymphnode.

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Claim 26 (original) The method of claim 25 wherein said protein comprises a secretion signal sequence.

Claim 27 (original) The method of claim 25 wherein said protein is a toxin.

Claim 28 (original) The method of claim 25 wherein said protein is ricin A chain or diphtheria toxin.

Claim 29. (previously presented) A method of delivering a desired protein to an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said desired protein, wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage,

wherein said DNA molecule is taken up by a macrophage cells and/or a cells of macrophage derived lineage where said nucleotide sequence is expressed to produce said desired protein in said macrophage cells and/or said cells of macrophage derived lineage.

Claim 30. (previously presented) The method of claim 25 wherein said promoter is a macrophage specific promoter.

Claim 31. (currently amended) ~~The method of claim 25~~ A method of eliminating cells in a lymphnode of an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule, wherein said DNA molecule is a plasmid, comprising a nucleotide sequence that encodes a cytotoxic protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in a macrophage cell and/or a

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cell of macrophage derived lineage, wherein said DNA molecule is taken up by a macrophage cells and/or a cells of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cells and/or said cells of macrophage derived lineage, said macrophage cell and/or a cell of macrophage derived lineage secretes or releases said cytotoxic protein in said lymphnode eliminating cells in said lymphnode.